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L8   L7 and @pd&lt;20030822   34   L8

L7   L6 and ((HFA adj 227) or (heptafluoropropane))   136   L7

L6   (mometasone adj furoate)   1150   L6

*DB=USPT; PLUR=YES; OP=OR*

L5   6365581.pn.   1   L5

*DB=PGPB,USPT; PLUR=YES; OP=OR*

L4   L3 and mometasone   30   L4

L3   Joel near Sequeira   51   L3

L2   Stefan near Sharpe   7   L2

*DB=PGPB; PLUR=YES; OP=OR*

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1: Clin Ther. 2000 Dec;22(12):1483-93.

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Full Text Article

## Regional lung deposition of a technetium 99m-labeled formulation of mometasone furoate administered by hydrofluoroalkane 227 metered-dose inhaler.

Pickering H, Pitcairn GR, Hirst PH, Bacon PR, Newman SP, Affrime MB, Marino M.

Pharmaceutical Profiles Ltd, Nottingham, United Kingdom.

**BACKGROUND:** A new inhaled suspension formulation of mometasone furoate (MF), a potent corticosteroid with minimal systemic availability, has been developed for the treatment of asthma. This formulation is delivered by metered-dose inhaler (MDI) using the nonchlorofluorocarbon propellant hydrofluoroalkane 227 (HFA-227). **OBJECTIVE:** The primary goal of this study was to determine the respiratory tract deposition of this formulation of MF. A secondary objective was to measure plasma concentrations of MF and a putative metabolite, 6-X-OH MF, to determine the systemic exposure to corticosteroid. **METHODS:** This was a single-dose, open-label study in which 200 microg of technetium 99m (99mTc)-radiolabeled MF was administered to patients with asthma. Gamma scintigraphy was used to quantify lung, oropharyngeal, stomach, and MDI mouthpiece deposition patterns of MF. **RESULTS:** Eleven patients, aged 21 to 47 years, with a history of asthma were enrolled in and completed the study. The mean (+/- SD) whole lung deposition of MF was 13.9% +/- 5.7% of the metered (ex-valve) dose. The central lung zone received 5.3% +/- 2.8% of the dose; the intermediate zone received 4.7% +/- 1.9%; and peripheral lung deposition was 4.0% +/- 1.5%. The mean (+/- SD) ratio of peripheral to central lung deposition was 0.8 +/- 0.2. Oropharyngeal deposition was 79.1% +/- 8.7% of the ex-valve dose, with 6.3% +/- 7.8% deposited on the MDI mouthpiece and 0.7% +/- 0.5% exhaled. The majority of plasma samples taken for analysis of MF and 6-13-OH MF concentrations were below the limit of quantification (50 pg/mL) in all patients after inhalation of 200 microg 99mTc-labeled ME. **CONCLUSION:** The lung deposition of MF when administered via HFA-227 MDI is comparable to the 10 to 20% lung deposition seen with other corticosteroid suspension formulations administered by MDI that have demonstrated effectiveness in the treatment of asthma.

Publication Types:

- Clinical Trial
- Historical Article